

SUNSCREEN- zinc oxide lotion

Plaine Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SUNSCREEN

Drug Facts

Active ingredient

Zinc oxide 18%

Purpose

Sunscreen

Uses

• helps prevent sunburn • if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use • on damaged or broken skin

When using this product • keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if • rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally and evenly 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

aloe vera (*Aloe barbadensis*) leaf juice, caprylic/capric triglyceride (Fractionated coconut oil), octyl palmitate, sorbitan sesquioleate, beeswax (*cera alba*), glycerin, glyceryl stearate, shea (*Butyrospermum parkii*) butter, PEG-30 dipolyhydroxystearate, sunflower (*Helianthus annuus*) seed oil, jojoba (*Simmondsia chinensis*) seed oil, castor (*Ricinus communis*) seed oil, white tea (*Camellia sinensis*) leaf extract, green tea (*Camellia sinensis*) leaf extract, mate (*Ilex paraguariensis*) leaf extract, rosemary (*Rosmarinus officinalis*) leaf oil, lavender (*Lavandula angustifolia*) oil, raspberry (*Rubus idaeus*) seed oil, rose hips (*Rosa canina*) fruit oil, avocado (*Persea gratissima*) oil, squalane, kukui nut (*Aleurites moluccana*) oil, tocopheryl acetate (vitamin E acetate), magnesium sulfate, xanthan gum, fragrance, caprylic acid, lauric acid, propanediol, potassium sorbate

Questions?

+1- 513-248-2017

You may also report serious side effects to this phone number. MON - FRI 9:00 AM - 5:00 PM

BROAD SPECTRUM SPF 30

RETURN ME I'M REUSABLE

WATER RESISTANT (40 MINUTES)

VEGAN, WATER RESISTANT, REEF SAFE, BIODEGRADABLE FORMULA, PALM OIL FREE, PARABEN FREE, KID SAFE

Crueltyfree

Thank you for helping stop the spread of single-use plastic.

WWW.PLAINEPRODUCTS.COM

Manufactured for: PLAINE PRODUCTS LLC, Cincinnati, OH 45174

Made in the USA

Packaging

SUNSCREEN

BROAD SPECTRUM SPF 30



plaine
products

WATER RESISTANT (40 MINUTES)

VEGAN | WATER RESISTANT | REEF SAFE | BIODEGRADABLE FORMULA
PALM OIL FREE | PARABEN FREE | KID SAFE

16 fl oz (1 pt) (473 mL)



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zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73757-411
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SHEA BUTTER (UNII: K49155WL9Y)	

PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
CASTOR OIL (UNII: D5340Y2I9G)	
WHITE TEA (UNII: O0M3396E09)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SQUALANE (UNII: GW89575KF9)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLIC ACID (UNII: OBL58JN025)	
LAURIC ACID (UNII: 1160N9NU9U)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73757-411-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2020	12/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/27/2020	12/31/2021

Labeler - Plaine Products (036831114)

Revised: 11/2021

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